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The Genetic Information Nondiscrimination Act of 2008 (GINA)

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Summary

On May 21, 2008, the Genetic Information Nondiscrimination Act of 2008 (GINA), referred to by its sponsors as the first civil rights act of the 21st century, was enacted. GINA, P.L. 110-233, prohibits discrimination based on genetic information by health insurers and employers. The sequencing of the human genome and subsequent advances raise hope for genetic therapies to cure disease, but this scientific accomplishment is not without potential problems. An employer or health insurer could decide to take adverse action based on a genetic predisposition to disease, and situations have arisen where discriminatory action based on genetic information did occur. In addition, there is evidence that the fear of genetic discrimination has an adverse effect on those seeking genetic testing, as well as on participation in genetic research. GINA was enacted to remedy this situation.

GINA is divided into two main parts: Title I, which prohibits discrimination based on genetic information by health insurers; and Title II, which prohibits discrimination in employment based on genetic information. Title I of GINA amends the Employee Retirement Income Security Act of 1974 (ERISA), the Public Health Service Act (PHSA), and the Internal Revenue Code (IRC), through the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as well as the Social Security Act, to prohibit health insurers from engaging in genetic discrimination. Title II of GINA prohibits discrimination in employment because of genetic information and, with certain exceptions, prohibits an employer from requesting, requiring, or purchasing genetic information. The law prohibits the use of genetic information in employment decisions—including hiring, firing, job assignments, and promotions—by employers, unions, employment agencies, and labor-management training programs.

This report provides background on genetic information, legal implications regarding the use of this information, and relevant laws. It also discusses the statutory provisions of GINA and the regulations regarding both health insurance and employment.

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Introduction

On May 21, 2008, the Genetic Information Nondiscrimination Act of 2008 (GINA), referred to by its sponsors as the first civil rights act of the 21st century, was enacted. GINA, P.L. 110-233, prohibits discrimination based on genetic information by health insurers and employers.

In April 2003, the sequence of the human genome was deposited into public databases. Scientists involved in the Human Genome Project (HGP)[1] reported that the finished sequence consists of overlapping fragments covering 99% of the coding regions of the human genome, with an accuracy of 99.999%.[2] These rapid advances provided resources for determining the causes of, and potentially the cures for, many common, complex diseases such as diabetes, heart disease, Parkinson's disease, bipolar disorder, and asthma. Specifically, scientists hoped that the data generated by the HGP would facilitate the identification of multiple genetic factors that influence a single disease or condition.

Although the sequence information was expected to help identify the genetic variants underlying disease and create a foundation for the development of genetic therapies, this scientific accomplishment raised certain considerations.[3] For instance, the presence of a specific genetic variation may indicate a predisposition to disease but does not guarantee that the disease will manifest. An employer or health insurer could decide to take adverse action based on a genetic predisposition, and situations have arisen where discriminatory action based on this type of genetic information did occur. In addition, the fear of this occurring could deter individuals both from seeking genetic testing and services, as well as from participating in genetic research. GINA was enacted to remedy this potential situation.

This report provides background on genetic research, considerations with the use and misuse of genetic information, and relevant law at the time of GINA's enactment. It also discusses the statutory provisions of GINA as enacted, the Department of Health and Human Services' (HHS's) regulations on health insurance, and the Equal Employment Opportunity Commission's (EEOC's) regulations on employment.[4]

[1] The Human Genome Project, begun in 1990, was a 13-year effort coordinated and funded by the U.S. Department of Energy and the National Institutes of Health to identify all of the protein-coding genes in human DNA; determine the sequence of the 3 billion chemical bases that make up human DNA; store this information in databases; develop tools for data analysis; and address the ethical, legal, and social issues (ELSI) that may arise from the project. For more detailed information see "The National Human Genome Research Institute," http://www.genome.gov/, and "Human Genome Project Information," http://www.ornl.gov/sci/techresources/Human_Genome/home.shtml.

[2] "International Human Genome Sequencing Consortium Describes Finished Human Genome Sequence," Oct., 20, 2004, at http://www.genome.gov/12513430.

[3] For more information on genetic testing and policy issues, see CRS Report RL33832, *Genetic Testing: Background and Policy Issues*, by Amanda K. Sarata. Also, for more information about federal oversight of genetic tests, see CRS Report R43438, *Regulation of Clinical Tests: In Vitro Diagnostic (IVD) Devices, Laboratory Developed Tests (LDTs), and Genetic Tests*, by Amanda K. Sarata and Judith A. Johnson.

[4] For a discussion of the Equal Employment Opportunity Commission (EEOC) regulations for Title II of GINA see CRS Report R41527, *The Genetic Information Nondiscrimination Act (GINA): Final Employment Regulations*.

Background

Human Genome Research

Almost all diseases have a genetic component and, therefore, genomic research has the potential to reduce the collective burden of diseases in the general population. Clinical genetic tests are becoming available at a rapid rate; in addition, private insurers are beginning to include some clinical genetic tests in their health insurance benefits packages as evidence of the tests' clinical validity and utility accumulates.[5] Most recently, genetic research has focused on precision medicine—a relatively new term for what has traditionally been called personalized medicine—the idea of providing health care to individuals based on specific patient characteristics, including genomic information. Researchers hope to combine genetic, environmental, clinical, behavioral, and other data to facilitate precision medicine. Precision medicine is a priority for the National Institutes of Health (NIH), which is carrying out a Precision Medicine Initiative. Part of this Initiative is the development of a national research cohort, composed of 1 million or more volunteers, whose health, genetic, environmental, and other data would be collected and used in research studies to identify novel therapeutics and prevention strategies.[6]

The HGP provided the foundational underpinnings for precision medicine. In congressional testimony, Dr. Francis Collins, then Director of the National Human Genome Research Institute (NHGRI) at the NIH, described the potential that the information generated by the HGP would likely have for clinical medicine and public health.[7] He stated that

> [T]he human genome sequence provides foundational information that now will allow development of a comprehensive catalog of all of the genome's components, determination of the function of all human genes, and deciphering of how genes and proteins work together in pathways and networks. Completion of the human genome sequence offers a unique opportunity to understand the role of genetic factors in health and disease, and to apply that understanding rapidly to prevention, diagnosis, and treatment. This opportunity will be realized through such genomics-based approaches as identification of genes and pathways and determining how they interact with environmental factors in health and disease, more precise prediction of disease susceptibility and drug response, early detection of illness, and development of entirely new therapeutic approaches.[8]

As Dr. Collins stated, with the completion of the human genome sequence, scientists turned their focus to better understanding the clinical and public health implications of the sequence information.

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[5] An example of this would be non-invasive prenatal tests (NIPTs); see, for example, https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/Tools%20and%20Resources/Policies%20and%20Protocols/Medical%20Policies/Medical%20Policies/Noninvasive_Prenatal_Diagnosis_of_Fetal_Aneuploidy.pdf.

[6] National Institutes of Health, "Precision Medicine Initiative," http://www.nih.gov/precisionmedicine/ and The White House, Office of the Press Secretary, "Fact Sheet: President Obama's Precision Medicine Initiative," January 30, 2015, http://www.whitehouse.gov/the-press-office/2015/01/30/fact-sheet-president-obama-s-precision-medicine-initiative.

[7] Dr. Collins stepped down as Director of the National Human Genome Research Institute to assume the position of Director of the National Institutes of Health. For more information on NHGRI, see http://www.genome.gov/.

[8] Testimony of Dr. Francis Collins, former Director, National Human Genome Research Institute, National Institutes of Health, Before the Subcommittee on Health of the House Committee on Energy and Commerce (May 22, 2003).

Concerns About the Potential Misuse of Genetic Information Leading Up to GINA

These scientific advances in genetic research, while promising, highlight the potential for misuse of the genetic information that such research generates. This concern, among other ethical, social, and legal implications of genetic research, was considered to be of enough import that a fixed portion of the total funds for the Human Genome Project were set aside to support the analysis and research of these issues.[9] As scientific knowledge about genetics was increasing leading up to the publication of the human genome sequence, researchers and commentators expressed concern about how this information may be used when it became available.[10] In congressional testimony, Dr. Collins stated

> [W]hile genetic information and genetic technology hold great promise for improving human health, they can also be used in ways that are fundamentally unjust. Genetic information can be used as the basis for insidious discrimination.... The misuse of genetic information has the potential to be a very serious problem, both in terms of people's access to employment and health insurance and the continued ability to undertake important genetic research.[11]

In the years before GINA was enacted, legal cases involving genetic discrimination were few.[12] However, studies have shown that public fear of discrimination existed prior to and after the enactment of GINA, and that it negatively influences the uptake of genetic testing and the use of genetic information by consumers and health professionals. The Secretary's Advisory Committee on Genetics, Health and Society (SACGHS) learned that 68% of Americans are concerned about who would have access to their personal genetic information; 31% state this concern would prevent them from having a genetic test; and 68% agree that insurers would do everything possible to use genetic information to deny health coverage.[13] A 2010 survey found that Americans are increasingly concerned about access to their genetic information; specifically, this survey found that 71% of Americans are concerned about storage of, and access to, their information, with the same percentage concerned specifically about access by health insurers.[14]

In addition, SACGHS as well as its predecessor committee, the Secretary's Advisory Committee on Genetic Testing (SACGT), sponsored two public forums in 2000 and 2004 to gather

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[9] The group working on these issues is referred to as the Ethical, Legal and Social Implications (ELSI) program. See http://www.genome.gov/page.cfm?pageID=10001618.

[10] Testimony by Dr. Francis Collins, former Director, National Center for Human Genome Research, before the Senate Committee on Labor and Human Resources (Mar. 6, 1996). See also, Hudson, Rothenberg, Andrews, Kahn, and Collins, "Genetic Discrimination and Health Insurance: An Urgent Need for Reform," *Science,* vol. 270, no. 391, Oct. 20, 1995; Annas, Glantz, and Roche, "Drafting the Genetic Privacy Act: Science, Policy and Practical Considerations," *Journal of Law, Medicine and Ethics,* vol. 23, no. 360, 1995; Gostin, "Genetic Discrimination: The Use of Genetically Based Diagnostic and Prognostic Tests by Employers and Insurers," *American Journal of Law & Medicine,* vol. 17, no. 109, 1991.

[11] Testimony of Dr. Francis Collins, former Director, National Human Genome Research Institute, National Institutes of Health, before the Senate Health, Education, Labor and Pensions Committee (July 20, 2000).

[12] For example, see *Norman-Bloodsaw v. Lawrence Berkeley Laboratory,* 135 F.3d 1260 (9th Cir. 1998), where blood tests for sickle cell trait were found to give rise to a claim under Title VII of the Civil Rights Act.

[13] Meeting of the Secretary's Advisory Committee on Genetics, Health, and Society, October 2005, http://osp.od.nih.gov/office-clinical-research-and-bioethics-policy/genetics-health-and-society/sacghs-archives/documents.

[14] Cogent Research, "Americans' Concern about the Privacy of Their Genetic Information Reaches New High," http://www.reuters.com/article/2011/01/10/idUS141239+10-Jan-2011+BW20110110.

perspectives on genetic discrimination. Many comments were received from patients, consumers, health professionals, scientists, genetic test developers, educators, industry representatives, policymakers, lawyers, students, and others representing a wide range of diverse ethnic and racial groups.[15] The comments and testimony revealed several anecdotal cases of discrimination. SACGT sent a letter to the Secretary of HHS after hearing about these cases from members of the public:

> During consultations with the public SACGT heard from many Americans who are concerned about the misuse of genetic information by third parties, such as health insurers and employers, and the potential for discrimination based on that information. Many stated that fear of genetic discrimination would dissuade them from undergoing a genetic test or participating in genetic research studies. Others stated that they would pay out of pocket for a genetic test to prevent the results from being placed in their medical record. Such concerns are a deterrent to advances in the field of genetic testing and may limit the realization of the benefits of genetic testing.[16]

A joint report by the Department of Labor, the Department of Health and Human Services, the Equal Employment Opportunity Commission (EEOC), and the Department of Justice (DOJ) summarized the various studies on discrimination based on genetic information. The report stated that "genetic predisposition or conditions can lead to workplace discrimination, even in cases where workers are healthy and unlikely to develop disease or where the genetic condition has no effect on the ability to perform work" and that "because an individual's genetic information has implications for his or her family members and future generations, misuse of genetic information could have intergenerational effects that are far broader than any individual incident of misuse."[17]

The National Council on Disability (NCD), an independent federal agency that advises the President and Congress on issues affecting individuals with disabilities, published a position paper on March 4, 2002 on genetic discrimination. The NCD stated that recent advances in genetic research have brought an increasing potential for genetic discrimination; that genetic discrimination is a historical and current reality; that genetic discrimination undermines the purposes of genetic research and testing; that genetic test information has little value for purposes of making employment decisions and insurance decisions; and that current law at the time was insufficient to protect individuals from genetic discrimination.[18]

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[15] Highlights and transcripts of Jan. 27, 2000, testimony can be found on the SACGT website at http://osp.od.nih.gov/office-clinical-research-and-bioethics-policy/genetics-health-and-society/sacgt-archives. Transcripts of the Oct. 18, 2004, testimony can be found on the SACGHS website at http://osp.od.nih.gov/office-clinical-research-and-bioethics-policy/genetics-health-and-society/sacghs-archives/documents.

[16] This quote was taken from a letter from SACGT to then Secretary of Health Tommy Thompson, May 3, 2001, at http://osp.od.nih.gov/office-clinical-research-and-bioethics-policy/genetics-health-and-society/sacgt-archives.

[17] Department of Labor, Department of Health and Human Services, Equal Employment Opportunity Commission, Department of Justice, "Genetic Information and the Workplace," January 20, 1998, http://www.dol.gov/oasam/programs/history/herman/reports/genetics.htm.

[18] National Council on Disability, "Position Paper on Genetic Discrimination Legislation," March 4, 2002, http://www.ncd.gov/publications/2002/March42002.

Federal Law Relating to Genetic Discrimination Prior to the Passage of GINA

Health Insurance Portability and Accountability Act of 1996 (HIPAA)

Title I of GINA extended the HIPAA protections against discrimination—by group health plans and issuers of health insurance in both the group and individual markets—as they were at the time GINA was enacted.[19] At the time of GINA's enactment, HIPAA prohibited a group health plan or issuer of a group health plan from using genetic information to establish rules for eligibility or continued eligibility and provided that genetic information shall not be treated as a preexisting condition in the absence of the diagnosis of the condition related to such information. HIPAA also prohibited a group health plan or issuer of a group health plan from using genetic information in setting a premium contribution. These protections applied to individuals within the group plans; however, they did not apply to the coverage of the whole group or to the premiums set for the group. Thus, HIPAA prohibited group health plans or issuers of group health plans from charging an individual a higher premium than a similarly situated individual; however, the law did not prevent an entire group from being charged more. The HIPAA nondiscrimination provisions did not apply to individual health insurance policies, and genetic information was able to be used to set premiums for individual policies (although HIPAA established both guaranteed issue for individuals who lose group coverage and guaranteed renewal for those with existing individual coverage). HIPAA also did not prevent group health plans or issuers of health plans from excluding coverage for a particular condition or imposing lifetime caps on all benefits, or on specific benefits.[20]

At the time of GINA's enactment, HIPAA did not prohibit group health plans or issuers of group health plans from requiring or requesting genetic information or testing.

Under the HIPAA Privacy Rule at the time of GINA's enactment, health plans and insurers were able to use or disclose health information for payment and other health care operations.[21] These included underwriting, premium rating, and other activities related to the creation, renewal, or replacement of an insurance contract.

Americans with Disabilities Act

The Americans with Disabilities Act (ADA)[22] prohibits discrimination against an individual with a disability in employment, public services, public accommodations, and communications. The

[19] HIPAA was amended and its protections were expanded by the Patient Protection and Affordable Care Act of 2010 (ACA, P.L. 111-148, as amended). For more information on the interaction between GINA and ACA, see CRS Report R41314, *The Genetic Information Nondiscrimination Act of 2008 and the Patient Protection and Affordable Care Act of 2010: Overview and Legal Analysis of Potential Interactions*, by Amanda K. Sarata and Jennifer A. Staman.

[20] HIPAA limited the circumstances under which a group health plan or insurer providing group health coverage may exclude a participant or beneficiary with a preexisting condition from coverage. This exclusion from coverage could not be for more than 12 months after an employee enrolls in a health plan (or 18 months for late enrollees). Further, this 12-month period could be offset by the number of days that an individual has "creditable coverage," with no "significant break" in this coverage (i.e., if after the termination of prior health coverage and before the enrollment date of the new coverage, there was not a 63-day continuous period in which the individual had no creditable coverage). See, e.g., 29 U.S.C. §1181.

[21] 45 C.F.R. §§500 et seq (2007).The HIPAA privacy and security standards are codified at 45 C.F.R. Part 164. The HIPAA Privacy and Security Rules established a set of federal standards to help safeguard personal health information.

[22] 42 U.S.C. §12101 et seq. For a detailed discussion of the ADA see CRS Report 98-921, *The Americans with*

threshold issue in any ADA case is whether the individual alleging discrimination is an individual with a disability. The ADA, as amended by the ADA Amendments Act of 2008,[23] defines the term disability with respect to an individual as having "(A) a physical or mental impairment that substantially limits one or more of the major life activities of such individual; (B) a record of such an impairment; or (C) being regarded as having such an impairment (as described in paragraph (3))."[24] Although the statutory language of the ADA does not reference genetic traits, there was a discussion of the issue during congressional debate of the original legislation.[25] Prior to GINA's enactment, there appears to have been no judicial decisions specifically dealing with genetic predisposition to disease and the ADA, but one case was brought by the EEOC and settled.[26] In another case, an individual filed with the EEOC alleging genetic discrimination and received a determination that the EEOC's investigation supported her allegation of discrimination under the ADA.[27]

Prior to the enactment of the ADA Amendments Act, the ADA's definition of "disability" had been interpreted by the EEOC to apply to individuals "who are subjected to discrimination on the basis of genetic information relating to illness, disease, or other disorders."[28] The legislative history was cited by the EEOC in its guidance to the definition of disability for its compliance manual. In this guidance, the EEOC examined the definition of disability under the ADA and concluded that the third prong—being regarded as having an impairment—prohibited discrimination based on genetic information relating to illness, disease, or other disorders.

Although this EEOC interpretation was widely heralded as a significant step for the protection of rights for individuals whose genes indicate an increased susceptibility to illness, disease, or other disorders, it was limited in its application and was further narrowed by Supreme Court decisions on the definition of disability.[29] However, at Senate hearings in 2002, EEOC Commissioner Paul

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Disabilities Act (ADA): Statutory Language and Recent Issues, by Cynthia Brown.

[23] P.L. 110-325.

[24] 42 U.S.C. §12102, as amended by P.L. 110-325. §4(a). For a more detailed discussion of the ADA Amendments Act see CRS Report RL34691, *The ADA Amendments Act: P.L. 110-325*.

[25] Rep. Owens stated that "[t]hese protections of the ADA will also benefit individuals who are identified through genetic tests as being carriers of a disease-associated gene. There is a record of genetic discrimination against such individuals, most recently during sickle cell screening programs in the 1970s. With the advent of new forms of genetic testing, it is even more critical that the protections of the ADA be in place." 136 Cong. Rec. H 4623 (daily ed. July 12, 1990) (remarks of Rep. Owens). Similarly, Rep. Edwards and Rep. Waxman also stated that individuals who are carriers of a disease-associated gene may not be discriminated against under the ADA. 136 Cong. Rec. H 4625 (daily ed. July 12, 1990) (Statement of Rep. Edwards); *Id*. at H 4627 (Statement of Rep. Waxman).

[26] The EEOC alleged that Burlington Northern Santa Fe (BNSF) Railroad tested its employees for a genetic marker linked to carpal tunnel syndrome in an attempt to address a high number of repetitive stress injuries leading to employee compensation. The EEOC and BNSF reached a settlement agreement rejecting the testing of employees for the genetic marker. See Paul Miller, EEOC commissioner, "Analyzing Genetic Discrimination in the Workplace," 12 Human Genome News (Feb. 2002) at http://www.ornl.gov/sci/techresources/Human_Genome/publicat/hgn/v12n1/09workplace.shtml.

[27] Testimony of Janiori Goldman before the House Committee on Energy and Commerce, Subcommittee on Health, 107th Cong., 1st sess. (Mar. 22, 2001).

[28] Equal Employment Opportunity Commission, Compliance Manual, vol. 2, section 902, order 915.002,902-45 (1995). It is also possible that Title VII of the Civil Rights Act of 1964, 42 U.S.C. §2000e et seq., may provide some protection against certain kinds of genetic discrimination since an argument could be made that discrimination based on genetic disorders that are more common in certain racial or ethnic groups, such as sickle cell disease, is prohibited under Title VII. There are relatively few genetic conditions that have a strong connection with a racial or ethnic group, thus limiting the scope of potential coverage. However, in *Norman-Bloodsaw v. Lawrence Berkeley Laboratory*, 135 F.3d 1260 (9th Cir. 1998), blood tests for sickle cell trait were found to give rise to a Title VII claim.

[29] See *Sutton v. United Airlines*, 527 U.S. 471 (1999); *Murphy v. United Parcel Service, Inc.*,527 U.S. 516 (1999).

Miller stated that the ADA "can be interpreted to prohibit employment discrimination based on genetic information. Nonetheless, the ADA does not explicitly address the issue and its protections are limited and uncertain."[30] In addition, Commissioner Miller observed that even if the ADA were found to cover genetic discrimination, the requirements of the ADA may not protect workers from all types of genetic discrimination. He stated, "for example, the ADA does not protect workers from requirements or requests to provide genetic information to their employers.... In addition, once the applicant is hired, the employer may request that the employee take a medical exam, such as a genetic test, if the employer can demonstrate that the information from that test is job related and consistent with business necessity."[31]

Although the combination of the ADA's legislative history and the EEOC's guidance raised the possibility that the ADA would cover genetic discrimination, this possibility remained uncertain since there had been no reported cases holding that the ADA prohibited genetic discrimination. This uncertainty increased after Supreme Court decisions on the definition of disability under the ADA, although the Supreme Court's decisions did not directly address ADA coverage of genetic discrimination.

The ADA Amendments Act rejected the Supreme Court's limited interpretation of the definition of disability and amended the ADA to provide for broader coverage. However, the ADA Amendments Act does not specifically mention genetic discrimination although the expanded definition would increase the likelihood of coverage. Thus, even if the ADA were found to cover genetic discrimination, GINA's protections are more targeted to protecting genetic information.

Executive Order

Executive Order 13145 currently prohibits discrimination against federal employees based on protected genetic information. The executive order defines "protected genetic information" as "(A) information about an individual's genetic tests; (B) information about the genetic tests of an individual's family members; or (C) information about the occurrence of a disease; or medical condition or disorder in family members of the individual." Current health status information would not be protected under this executive order unless it was derived from the information described above. The EEOC has issued guidance on the executive order.[32]

Genetic Information Nondiscrimination Act of 2008 (GINA)

Overview of GINA's Statutory Provisions

GINA contains a statement of findings which discusses the significance of the sequencing of the human genome, the history of discrimination based on genetics, and the inadequacy of current federal and state laws. The statute is then divided into three titles: Title I, which prohibits genetic discrimination in health insurance; Title II, which prohibits genetic discrimination in

[30] Statement of Commissioner Paul Steven Miller, U.S. Equal Employment Opportunity Commission, before the Senate Committee on Health, Education, Labor and Pensions, July 20, 2000.

[31] Ibid.

[32] EEOC, "Policy Guidance on Executive Order 13145: To Prohibit Discrimination in Federal Employment Based on Genetic Information," http://www.eeoc.gov/policy/docs/guidance-genetic.html.

employment; and Title III, which contains miscellaneous provisions on severability and child labor protections.

Definition of Genetic Information

One of the most discussed provisions of GINA was the definition of genetic information. Discussions were focused on decisions that would impact the term's scope, centering largely on the exclusions for the definition (i.e., basic demographic information that implies genetic information, such as sex) as well as how to incorporate the concept of family history. Specifically, the definition of genetic information relies on three terms, two defined in the law—"genetic test" and "family member"—and one added through regulation, "manifestation" or "manifested." Together, these terms serve to delineate the scope of the law's protections.

Both Title I and Title II contain a definition of genetic information which states the following (key terms are in bold, emphasis added)

> GENETIC INFORMATION-(A) IN GENERAL -The term 'genetic information' means, with respect to any individual, information about—(i) such individual's **genetic tests**, (ii) the genetic tests of **family members** of such individual, and (iii) the **manifestation** of a disease or disorder in family members of such individual.(B) INCLUSION OF GENETIC SERVICES AND PARTICIPATION IN GENETIC RESEARCH -Such term includes, with respect to any individual, any request for, or receipt of, genetic services, or participation in clinical research which includes genetic services, by such individual or any family member of such individual. (C) EXCLUSIONS -The term 'genetic information' shall not include information about the sex or age of any individual.[33]

Regulations have been promulgated implementing both titles of GINA. The Departments of Health and Human Services, Treasury, and Labor jointly issued interim final regulations with request for comments implementing Sections 101 through 103 of Title I of GINA,[34] excluding Section 104 ("Amendments to title XVIII of the Social Security Act relating to medigap") and Section 105 ("Privacy and confidentiality"). The Department of Health and Human Services, Office for Civil Rights, issued a final rule to implement Section 105,[35] and Section 104 incorporates, by reference to the Social Security Act, Section 1882, provisions of a model National Association of Insurance Commissioners (NAIC) regulation which addresses Medigap issuers.[36] Additionally, the Equal Employment Opportunity Commission (EEOC) has issued regulations for Title II of GINA.[37]

All of these regulations follow the statutory definition for "genetic information." The EEOC regulations clarify that neither race nor ethnicity (if this information is not derived from genetic tests) are considered to be genetic information.[38]

[33] 42 U.S.C. §2000ff(4).

[34] 74 *Federal Register* 51664 (October 7, 2009). It does not appear that HHS has issued a final rule subsequent to this interim final rule; however, the interim final regulations still have legal effect.

[35] 78 *Federal Register* 5566 (January 25, 2013).

[36] 74 *Federal Register* 18808 (April 24, 2010).

[37] 75 *Federal Register* 68912 (November 9, 2010).

[38] 75 *Federal Register* 68916 (November 9, 2010).

Definition of Genetic Test

As is the case with the definition for the term genetic information, the definition of genetic test is also of pivotal importance to defining the scope, and ultimately determining the impact, of the nondiscrimination protections in GINA. Importantly, this definition is different in Title I and Title II of the act. The Title I definition exempts genetic tests that are "an analysis of proteins or metabolites that [are] *directly related to a manifested disease, disorder, or pathological condition* that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved."[39] Title II defines genetic test as

> (A) IN GENERAL.—The term "genetic test" means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detects genotypes, mutations, or chromosomal changes.
>
> (B) Exceptions.—The term "genetic test" does not mean an analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes.[40]

While Title II does not include the exception regarding manifested diseases contained in Title I, it does contain Section 210, which states,

> An employer, employment agency, labor organization, or joint labor-management committee shall not be considered to be in violation of this title based on the use, acquisition, or disclosure of medical information that is not genetic information about a manifested disease, disorder, or pathological condition of an employee or member, including a manifested disease, disorder, or pathological condition that has or may have a genetic basis.[41]

The interim final regulations follow the statutory language with respect to the definition of genetic test except that they provide specific examples of genetic and non-genetic tests to illustrate the definition's scope.

The EEOC's final regulations also mirror the statutory language except that the regulations provide specific examples of genetic tests and of tests or procedures that are not genetic tests. For example, a genetic test includes a test to determine whether an individual has a BRCA1 or BRCA2 variant, which would indicate a predisposition to breast cancer, and would also include preimplantation genetic diagnosis on embryos.[42] One of the examples given in the regulations of a test that is not a genetic test is a test for cholesterol levels, since a cholesterol test does not detect mutations. Similarly, testing for the presence of alcohol or illegal drugs is also not considered a genetic test since it is not an analysis of DNA or RNA; however, a test to determine whether an individual has a genetic predisposition for alcoholism or drug use is a genetic test.[43]

Genetic Nondiscrimination and Health Insurance

Overview of Health Insurance Provisions

Title I of GINA strengthens and clarifies existing HIPAA nondiscrimination and portability provisions through amendments to the Employee Retirement Income Security Act of 1974 (ERISA), the Public Health Service Act (PHSA), and the Internal Revenue Code (IRC), as well as

[39] See, for example, 42 U.S.C. §9832(d)(8)(B)(ii).

[40] 42 U.S.C. §2000ff(7).

[41] 42 U.S.C. §2000ff-9.

[42] 29 C.F.R. §1635.3(f)(2); 75 *Federal Register* 68933 (November 9, 2010).

[43] 29 C.F.R. §1635.3(f)(3); 75 *Federal Register* 68933 (November 9, 2010).

to the Social Security Act (SSA). In this way, group plans under ERISA, group and individual plans under the PHSA, Church Plans under the IRC, and Medigap plans under the SSA are all brought under the jurisdiction of the law. The complexity of the health care financing system required this approach to extend protection to all covered individuals, regardless of their insurance situation. The HHS interim final regulations implement Sections 101, 102, and 103 of Title I of GINA; as mentioned above, they do not address the application of GINA to Medigap issuers nor do they implement Section 105 of the title.[44]

Prohibited Health Insurer Practices

Broadly, GINA prohibits health insurers from engaging in three practices: (1) using genetic information about an individual to adjust a group plan's premiums, or, in the case of individual plans, to deny coverage, adjust premiums, or impose a preexisting condition exclusion; (2) requiring or requesting genetic testing; and (3) requesting, requiring, or purchasing genetic information for underwriting purposes. Each of these provisions is discussed below in more detail, and where applicable, modifications made by the regulations are noted.

Discrimination in Premium Setting and Eligibility Prohibited

GINA prohibits health plans, group and individual health insurers and issuers, and issuers of Medicare supplemental policies from adjusting a group or individual's premium based on genetic information about an individual in the group, an individual seeking individual coverage, or an individual's family members. It also prohibits individual insurers from conditioning eligibility or continuing eligibility on genetic information, and prohibits individual insurers from treating genetic information as a preexisting condition. Issuers of supplemental Medicare policies may not deny or condition the issuance of a policy based on genetic information (and may not impose a preexisting condition exclusion based on genetic information).

Genetic Testing Requests or Requirements Prohibited

GINA prohibits health plans, group and individual health insurers and issuers, and issuers of Medicare supplemental policies from requesting or requiring that individuals or their family members undergo a genetic test. This prohibition does not limit the authority of a health care professional to request that an individual undergo genetic testing as part of his or her course of health care. The act provides for a research exception to this provision, by allowing a group or individual insurance issuer to request, but not require, an individual to undergo genetic testing if specific conditions are met.

Collection and Use of Genetic Information Restricted

GINA prohibits health plans, group and individual health insurers and issuers, and issuers of Medicare supplemental policies from requesting, requiring, or purchasing genetic information for the purposes of underwriting prior to an individual's enrollment or in connection with enrollment. "Incidental collection" of genetic information would not be considered a violation. The HHS final interim rules clarify that "purposes of underwriting" does not include a request for family history or other genetic information to make a determination whether a benefit is medically appropriate for purposes of payment.[45]

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[44] 74 *Federal Register* 51665 (October 7, 2009).

[45] 74 *Federal Register* 51668 (October 7, 2009).

Application to Genetic Information of a Fetus or Embryo

Title I of the act clarifies that genetic discrimination based on the genetic information of either the fetus of a pregnant woman or an embryo legally held by an individual or family member is prohibited. The HHS interim final regulations do not modify this provision.[46]

Rule of Construction

GINA provides clearly that nothing in the act should be construed to preclude the use of information about a manifested disease or disorder in an individual (or an individual's family member) by health plans, group and individual health insurers and issuers, and issuers of Medicare supplemental policies to establish premiums or conditions of eligibility. The HHS interim final regulations additionally clarify that insurers may not utilize the manifestation of a disease in an individual in a group as genetic information about other group members in determining the premium (for example, in the case of family members covered under the same policy, where the manifestation of a disease or condition in an individual might be relevant to the other family members' risk of manifesting that same disease or condition).[47] In addition, nothing in the act should be construed to prohibit health plans, group and individual health insurers and issuers, and issuers of Medicare supplemental policies from obtaining or using the results of genetic tests to determine payment. However, only the minimum amount of information required to achieve this purpose may be requested. HHS's interim final regulations clarify that where the appropriateness of a treatment depends on the patient's genetic makeup, an insurer may condition payment on the results of a genetic test or may deny payment for the treatment in the absence of the genetic test.[48] A double mastectomy, for example, might be indicated for an individual without a personal history of breast cancer only in the presence of a positive BRCA1/2 genetic test result; an insurer might not cover the surgical procedure only in the presence of family history of disease but in the absence of a confirmatory genetic test. However, the rules explain that in a case like this, the use of the genetic information to determine payment would not be a violation of GINA.

Privacy and Confidentiality

GINA directs the Secretary of Health and Human Services to revise the HIPAA Privacy Rule[49] to reflect that genetic information shall be treated as health information and the use or disclosure by a covered entity of protected health information (i.e., genetic information) for the purposes of underwriting shall not be a permitted use or disclosure.[50] The Secretary, in consultation with the Secretaries of Labor and the Treasury, had 12 months after enactment of the act to issue final regulations to carry out these revisions.

On January 25, 2013, the Department of Health and Human Services, Office for Civil Rights, published a final rule to implement Section 105 of GINA. Among other things, the final rule modified the HIPAA Privacy Rule to prohibit all health plans that are covered entities under the HIPAA Privacy Rule from using or disclosing protected health information, which is genetic information, for purposes of underwriting. The HIPAA Privacy Rule defines as covered entities several types of "health plans" to which GINA does not expressly apply, including (1) long-term

[46] 74 *Federal Register* 51679 (October 7, 2009).

[47] 74 *Federal Register* 51680 (October 7, 2009).

[48] 74 *Federal Register* 51687 (October 7, 2009).

[49] 45 C.F.R. Part 46.

[50] 42 U.S.C. §1320d-9.

care policies; (2) employee welfare benefit plans; (3) certain high risk pools; (4) certain public benefit programs, such as Medicare Part A and B, Medicaid, and the Indian Health Service (IHS); and (5) any other individual or group plan, that provides or pays for the cost of medical care.[51] The final rule clarifies that despite the statutory language of GINA only referencing those covered entities that are group health plans, a group and individual health insurance issuers, or an issuer of a Medicare supplemental policy, the prohibition on using or disclosing genetic information for underwriting purposes extends to *all* of the additional entities in the HIPAA Privacy Rule's definition of "health plan" *except* for issuers of long-term care policies.[52]

Additionally, under the terms of the final rule, the use of an individual's genetic information for underwriting purposes is barred even if authorized by an individual,[53] and requires health plans that perform underwriting to include in their Notice of Privacy Practices (NPPs) that they are prohibited from using health information, that is genetic information, for purposes of underwriting.[54]

Remedies and Enforcement

For group health plans and health insurance issuers offering group health insurance in the large and small group markets, GINA permits the imposition of penalties for failures to comply with the nondiscrimination requirements relating to genetic information in GINA (see "Prohibited Health Insurer Practices").[55]

GINA authorized the Secretary to impose a penalty of $100 per day per beneficiary or participant to whom the failure relates during a period of noncompliance with the provisions in Title I. Where willful neglect was found, GINA establishes a minimum penalty of $2,500, or $15,000 for more severe or prolonged violations.

There are three limitations to the penalties that may be imposed by the Secretary. First, the penalty does not apply if the Secretary determines that the person otherwise liable for the penalty did not know (and, exercising reasonable diligence, would not have known) that the noncompliance occurred. Second, the penalty does not apply to failures corrected within 30 days (in cases not due to willful neglect). Finally, a limit to the total penalty for certain unintentional failures must not exceed the lesser of $500,000 or 10% of the aggregate amount paid or incurred by the plan sponsor during the preceding year for group health plans. The statute also provides the Secretary with waiver authority, if the penalty is deemed excessive relative to the failure involved.

The HHS interim final regulations are silent on the HHS and DOL secretarial enforcement authorities regarding the use of genetic information that were added under GINA; these will be addressed through future regulatory guidance.[56]

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[51] The final rule clarifies that this final category of plan—any other group or individual plan that provides or pays for the cost of medical care—includes, for example, limited scope dental or vision plans. See 78 *Federal Register* 5659 (January 25, 2013).

[52] 78 *Federal Register* 5659-5660 (January 25, 2013).

[53] 78 *Federal Register* 5666 (January 25, 2013).

[54] 78 *Federal Register* 5568 (January 25, 2013).

[55] For issuers of health insurance coverage in the individual market, GINA referenced existing enforcement authorities found at PHSA Section 2722(b)(2). GINA §102(b).

[56] 74 *Federal Register* 51665 (October 7, 2009).

Genetic Nondiscrimination and Employment

Overview of Employment Provisions

GINA prohibits discrimination in employment because of genetic information and, with certain exceptions, prohibits an employer from requesting, requiring, or purchasing genetic information. The law prohibits the use of genetic information in employment decisions, including hiring; firing; job assignments; and promotions by employers, unions, employment agencies, and labor-management training programs. The EEOC has issued regulations for Title II that generally track the statutory language.[57]

Definition of Employee and Employer

GINA defines employees and employers as those defined in Title VII of the Civil Rights Act of 1964,[58] a state employee or employer as defined in Section 304(a) of the Government Employee Rights Act of 1991,[59] and a covered employee or employing office as defined in Section 101 of the Congressional Accountability Act.[60] Generally, this includes employees and applicants working in the private sector for an employer who employs 15 or more employees, federal and state governments, as well as congressional employees. The corresponding employers of these individuals, as well as employment agencies, labor organizations, and training programs, also are covered by the law. The EEOC's regulations echo the statutory language regarding employees and also include former employees.[61]

Prohibited Employment Practices

As noted previously, GINA prohibits the use of genetic information in employment decisions, including hiring, firing, job assignments, and promotions by employers, labor unions, employment agencies, and labor-management training programs. In addition, an employer, employment agency, labor union, or training program may not "request, require or purchase genetic information" with respect to the employee, individual, union member, or family member.[62]

Exceptions to Prohibited Practices

There are statutory exceptions to the prohibition on the acquisition of genetic information for employers, employment agencies, labor unions, and training programs.[63] However, GINA

[57] 75 *Federal Register* 68912 (November 9, 2010). For a discussion of these regulations see CRS Report R41527, *The Genetic Information Nondiscrimination Act (GINA): Final Employment Regulations*.

[58] 42 U.S.C. §§2000e(b), (f). Most federal employment discrimination laws are patterned on Title VII, which prohibits employment discrimination on the basis of race, color, national origin, religion, or sex.

[59] 42 U.S.C. §2000e-16c(a).

[60] 2 U.S.C. §1301.

[61] 29 C.F.R. §1635.2(c); 75 *Federal Register* 68932 (November 9, 2010). The Supreme Court in Robinson v. Shell Oil Co., 519 U.S. 337, 346 (1997), held that the term "employee" under Title VII, which is referenced in the definition in GINA, includes former employees.

[62] 42 U.S.C. §2000ff-1(a)-(b)(employers); 42 U.S.C. §2000ff-2(a)-(b)(employment agencies); 42 U.S.C. §2000ff-3(a)-(b)(labor organizations); 42 U.S.C. §2000ff-4(a)(b)(training programs).

[63] 42 U.S.C. §2000ff-1(b)(employers); 42 U.S.C. §2000ff-2(b)(employment agencies); 42 U.S.C. §2000ff-3(b)(labor organizations); 42 U.S.C. §2000ff-4(b)(training programs).

provides that, even if an exception applies, genetic information may not be used in a manner that violates nondiscrimination or confidentiality requirements.[64]

Inadvertent Requests

The first exception applies when one of these entities inadvertently requests or requires family medical history of the employee, individual, union member, or a family member. The House Education and Labor Report noted that this exception "addresses the so-called 'water cooler' problem, in which an employer unwittingly receives otherwise protected genetic information in the form of family medical history through casual conversations with a worker."[65] Family medical history is not defined in the statute but the EEOC regulations define the term as meaning "information about the manifestation of disease or disorder in family members of the individual."[66]

Wellness Programs

The second exception is for health or genetic services offered by the entity as part of a wellness program.[67] To qualify for the exception

- the employee, individual or union member must provide prior, knowing, voluntary, and written authorization;
- only the employee, individual, union member, or family member and the licensed health care professional or board certified genetic counselor involved in providing such services can receive individually identifiable information concerning the results of the services; and
- any individually identifiable genetic information is only available for such services and shall not be disclosed to the employer except in aggregate terms that do not identify individuals.

The EEOC regulations reiterate the exception and its requirements[68] but also provide that inducements may be offered to encourage individuals to participate in wellness programs. However, these inducements may not be offered to provide genetic information. The EEOC provides the following example in the regulations as a situation that does not violate GINA:

> A covered entity offers $150 to employees who complete a health risk assessment with 100 questions, the last 20 of them concerning family medical history and other genetic information. The instructions for completing the health risk assessment make clear that the inducement will be provided to all employees who respond to the first 80 questions, whether or not the remaining 20 questions concerning family medical history and other genetic information are answered.[69]

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[64] 42 U.S.C. §2000ff-1(c)(employers); 42 U.S.C. §2000ff-2(c)(employment agencies); 42 U.S.C. §2000ff-3(c)(labor organizations); 42 U.S.C. §2000ff-4(c)(training programs).

[65] H.Rept. 110-28, Part 1 at 37 (March 5, 2007).

[66] 29 C.F.R. §1635.3(b); 75 *Federal Register* 68933 (November 9, 2010).

[67] For a discussion of the legal issues involving wellness programs generally, see CRS Report R40661, *Wellness Programs: Selected Legal Issues*.

[68] 29 C.F.R. §1635.8(b)(2), 75 *Federal Register* 68935 (November 9, 2010).

[69] 29 C.F.R. §1635.8(b)(2)(ii)(A), 75 *Federal Register* 68935 (November 9, 2010).

In contrast, if the health risk assessment does not make clear which questions must be answered, it would violate GINA.[70]

The regulations also provide that they do not limit the rights or protections available under the ADA, other civil rights laws, or HIPAA. For example, an employer must make reasonable accommodations, as required under the ADA to enable a person with a disability to participate in a wellness program.

Finally, it is important to note that several provisions in the Patient Protection and Affordable Care Act of 2010 (ACA, P.L. 111-148, as amended) address wellness programs. Although the EEOC has indicated that it eventually intends to issue regulations on the subject, it is currently unclear how these provisions interact with the wellness provisions in GINA.[71] In the meantime, the EEOC recently sued a company based on allegations that its wellness program violated the statute's prohibition against genetic information discrimination. Although the case has not yet been decided, the court noted in a preliminary ruling that "great uncertainty persists in regard to how the ACA, ADA and other federal statutes such as GINA are intended to interact."[72]

Certification Procedures Under Medical Leave Laws

The third statutory exception is for information necessary for certification procedures under federal and state family and medical leave laws. This exception was described as "eliminat[ing] the potential for conflict with existing laws."[73] The EEOC regulations track the statutory provisions.[74]

Inadvertent Acquisition of Genetic Information by Purchase of Documents

The fourth exception, like the first, concerns the inadvertent acquisition of genetic information by the purchase of documents, such as newspapers, that are commercially and publicly available and that include family medical history. This exception was intended to address the concern that GINA could be violated by such actions as the purchase of a newspaper "containing the obituary of an employee's parent who died of breast cancer."[75] The EEOC's regulations include electronic media, such as the Internet, television, and movies, as potential sources of genetic information.[76] In its discussion of this exception, the EEOC examines the factors used in deciding whether a document is commercially or publicly available and determines that the key criterion is "whether access requires permission of an individual or is limited to individuals in a particular group, not whether the source is categorized as a social networking site, personal Web site, or blog."[77] The EEOC also notes that the exception does not apply to genetic information gathered by actively searching for genetic information from commercially and publicly available sources, or to the

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[70] 29 C.F.R. §1635.8(b)(2)(ii)(B), 75 *Federal Register* 68935 (November 9, 2010).

[71] For more information about this potential interaction, see CRS Report R41314, *The Genetic Information Nondiscrimination Act of 2008 and the Patient Protection and Affordable Care Act of 2010: Overview and Legal Analysis of Potential Interactions*, by Amanda K. Sarata and Jennifer A. Staman.

[72] Equal Emp't Opportunity Comm'n v. Honeywell Int'l, Inc., 2014 U.S. Dist. LEXIS 157945, *13 (D. Minn. Nov. 6, 2014).

[73] H.Rept. 110-28, Part 1 at 38 (March 5, 2007).

[74] 29 C.F.R. §1635.8(b)(3), 75 *Federal Register* 68936 (November 9, 2010).

[75] *Id.*

[76] 29 C.F.R. §1635.8(b)(4), 75 *Federal Register* 68936 (November 9, 2010).

[77] 75 *Federal Register* 68925 (November 9, 2010).

acquisition of genetic information from a source likely to contain such information, such as a website that focuses on genetic testing.[78]

Genetic Monitoring of Toxic Substances

The fifth exception applies when the information involved is to be used for genetic monitoring of the biological effects of toxic substances in the workplace.[79] However, in order for this exception to apply

- the employer, employment agency, labor union, or training program must provide written notice of the genetic monitoring to the employee;
- the employee, individual, or union member must provide prior, knowing, voluntary, and written authorization; or the genetic monitoring is required by federal or state law;
- the employee, individual, or union member must be informed of individual monitoring results;
- the monitoring must be in compliance with federal genetic monitoring regulations, or state genetic monitoring regulations; and
- the employer, employment agency, labor union, or training program, excluding any licensed health care professional or board certified genetic counselor, must receive the results only in aggregate terms that do not disclose the identity of specific employees.

DNA Analysis for Law Enforcement Purposes

There is a sixth exception for employers and training programs but not for employment agencies or labor unions. This exception allows employers and training programs that conduct DNA analysis for law enforcement purposes as a forensic laboratory or for purposes of human remains identification to request or require genetic information from their employees, but only when it is used for analysis of DNA identification markers for quality control to detect sample contamination. The EEOC notes that this is a very limited exception.[80]

Confidentiality of Genetic Information

Generally, GINA requires that genetic information shall be maintained on separate forms and in separate medical files and be treated as a confidential medical record.[81] The statute also prohibits employers, employment agencies, labor unions, and joint labor-management committees from disclosing genetic information. These entities are considered to be in compliance with the maintenance of information requirements if the genetic information is treated as a confidential record under the ADA.[82] However, the general prohibition on disclosure is subject to six exceptions. Genetic information may be disclosed

- to the employee or member of a labor union (or family member receiving genetic services) at the written request of the employee or member;

[78] *Id.*

[79] 29 C.F.R. §1635.8(b)(5), 75 *Federal Register* 68936 (November 9, 2010).

[80] 29 C.F.R. §1635.8(b)(6), 75 *Federal Register* 68936 (November 9, 2010).

[81] 42 U.S.C. §2000ff-5.

[82] 42 U.S.C. §12112(d)(3)(B).

- to an occupational or other health researcher if the research is conducted in compliance with 45 C.F.R. Part 46, which provides for protection of human research subjects;
- in response to a court order except that only the genetic information expressly authorized by the order shall be disclosed; if the court order was obtained without the knowledge of the employee or member to whom the information refers, the employee or member shall be informed of the court order and the information may be disclosed;
- to government officials who are investigating compliance with Title II of GINA, if the information is relevant;
- where such disclosure is made in connection with the certification provisions of the Family and Medical Leave Act or state family and medical leave laws; or
- to a federal, state, or local public health agency regarding a contagious disease that presents an imminent hazard of death or life-threatening illness, and there is notification.[83]

GINA also contains a provision concerning the relationship of the confidentiality provisions with the HIPAA Privacy Rule. GINA does not prohibit an entity covered under HIPAA "from any use or disclosure of health information that is authorized for the covered entity under such regulations."[84]

The EEOC final regulations track the legislative language.[85] The EEOC in its discussion of the final regulations addresses several concerns raised by commenters. For example, the EEOC states that genetic information that had been placed in a personnel file prior to the effective date of GINA, need not be removed and its existence does not create a violation of GINA. However, disclosing such information to a third party would violate the law.[86]

Remedies and Enforcement

Generally, GINA uses the remedies and enforcement mechanisms available under Title VII of the Civil Rights Act of 1964,[87] although for employees covered by the Government Employee Rights Act of 1991, the Congressional Accountability Act of 1995, chapter 5 of Title 3 of the U.S. Code, or Section 717 of the Civil Rights Act of 1964, the remedies and procedures track those Acts and statutory provisions. These remedies include compensatory and punitive damages, reasonable attorney's fees, including expert fees, and injunctive relief, including reinstatement and hiring, back pay, and other equitable remedies.[88]

In general, individuals who believe they are the victims of employment discrimination based on genetic information must file a complaint with the EEOC, which is responsible for enforcing individual Title VII claims against private employers.[89] If the EEOC declines to take action or if

[83] 42 U.S.C. §2000ff-5(b).

[84] 42 U.S.C. §2000ff-5(c).

[85] 29 C.F.R. §1635.9, 75 *Federal Register* 68937 (November 9, 2010).

[86] 75 *Federal Register* 68927 (November 9, 2010).

[87] 42 U.S.C. §§2000e-4 et seq.

[88] 29 C.F.R. §1635.10(b), 75 *Federal Register* 68938 (November 9, 2010), referring to 42 U.S.C. §§1981a(a)(1), (b); 1988(b); 2000e-5(q).

[89] 42 USCS §2000e-5.

the agency's efforts to reach a voluntary settlement with the employer fail, an individual may file suit in federal court. The EEOC may also independently file a lawsuit against an employer.[90]

According to the EEOC, the agency received 88,778 complaints of employment discrimination in FY2014.[91] Of those, only 333 were claims based on GINA.[92] As a result, it appears there have been only a limited number of cases that have reached federal court. Meanwhile, the EEOC has independently pursued several cases against employers.[93]

Disparate Impact

Under Title VII, an employee may file a disparate impact claim if he believes that a neutral employment policy or practice has had a disparate impact based on race, color, religion, sex, or national origin.[94] In contrast, GINA specifically provides that such disparate impact does not create a cause of action under its provisions. However, GINA requires that a commission be established six years after the date of enactment to review the science of genetics and make recommendations to Congress regarding whether to provide a disparate impact cause of action under GINA.[95]

Construction

Section 209 of GINA contains several rules of construction, including a provision concerning the relationship between Title I and Title II of the act. GINA provides that nothing in Title II is to be construed to limit the rights or protections of an individual under any federal or state statute that provides equal or greater protection. In addition, nothing in Title II is to limit the rights or protections of an individual to bring an action, or provide for enforcement of, or penalties for, any violation under Title I of GINA, certain sections of ERISA, the Public Health Service Act, and the Internal Revenue Code. This provision has been referred to as a "firewall" between Titles I and II, and has been described as clarifying "that employers are not liable for health insurance violations under civil rights laws unless the employer has separately violated a provision of Title II governing employers."[96]

GINA also states that it does not

- apply to the Armed Forces repository of specimen samples for the identification of remains;
- limit or expand the protections, rights, or obligations of employees or employers under applicable workers' compensation laws;

[90] *Id.*

[91] Equal Employment Opportunity Commission, *All Statutes FY1997-FY2014*, http://www.eeoc.gov/eeoc/statistics/enforcement/all.cfm.

[92] Equal Employment Opportunity Commission, *Genetic Information Non-Discrimination Act Charges FY 2010-2014*, http://www.eeoc.gov/eeoc/statistics/enforcement/genetic.cfm.

[93] For example, in 2013, the EEOC filed—and simultaneously settled—its first lawsuit based on GINA. Equal Emp't Opportunity Comm'n v. Fabricut, No. 13·CV.24S·CVE.PJC (N.D. Okla. May 7, 2013). *See also*, Equal Employment Opportunity Commission, *Fabricut to Pay $50,000 to Settle EEOC Disability and Genetic Information Discrimination Lawsuit*, Press Release, May 7, 2013, http://www.eeoc.gov/eeoc/newsroom/release/5-7-13b.cfm; Equal Employment Opportunity Commission, *Founders Pavilion Will Pay $370,000 to Settle EEOC Genetic Information Discrimination Lawsuit*, Press Release, Jan. 13, 2014, http://www.eeoc.gov/eeoc/newsroom/release/1-13-14.cfm; Equal Emp't Opportunity Comm'n v. Honeywell Int'l, Inc., 2014 U.S. Dist. LEXIS 157945, *13 (D. Minn. Nov. 6, 2014).

[94] 42 U.S.C. §2000e-2(k).

[95] 42 USCS §2000ff-7.

[96] 154 Cong. Rec. H2972 (daily ed. May 1, 2008)(statement of Rep. Dingell).

- limit the authority of a federal department or agency to conduct or sponsor health research conducted in compliance with rules for research on human subjects;
- limit the statutory or regulatory authority of the Occupational Safety and Health Administration or the Mine Safety and Health Administration regarding workplace safety and health laws and regulations; or
- require any specific benefit for an employee or member or a family member under any group health plan.

Section 209 also specifies that any reference in Title II to genetic information concerning an individual or family member also includes the genetic information of any fetus carried by a pregnant woman. In addition, genetic information on any embryo legally held by the individual or family member would also be included in the reference to genetic information.

Finally, Section 209 provides that Title II does not prohibit the activity of a group health plan or health insurance issuer offering group health insurance coverage that is authorized by Title I, and certain sections of ERISA, the Public Health Service Act, and the Internal Revenue Code.

Manifested Diseases

Section 210 of GINA clarifies that the act does not cover medical information that is not genetic information about a manifested disease, disorder, or pathological condition, including a manifested disease, disorder, or pathological condition that has or may have a genetic basis. The final EEOC regulations elaborate on the statutory language, specifically stating that "the acquisition, use, and disclosure of medical information that is not genetic information about a manifested disease, disorder, or pathological condition is subject to applicable limitations" under the ADA.[97] In its discussion of the final regulations, the EEOC notes that one commenter had expressed concern that individuals who have a manifested genetic disease that is not yet substantially limiting may not be covered under either law. The EEOC declined to address this issue, stating that it had no authority to expand the coverage of GINA. However, the EEOC observed that with the enactment of the ADA Amendments Act (ADAAA),[98] which expanded the definition of disability under the ADA, it is less likely that there would be a significant number of individuals who would not be covered by either Act.[99]

Both the EEOC rules and the HHS interim final rules add a definition for the terms "manifestation" and "manifested." Specifically, the rules define these terms to mean a disease, disorder, or pathological condition that has been or could "reasonably be diagnosed by a health care professional with appropriate training and expertise in the field of medicine involved." The rules add further that a "disease, disorder, or pathological condition is not manifested if a diagnosis is based principally on genetic information."[100]

The addition of these definitions may address the above concern regarding those individuals with a manifested genetic disease that is not yet substantially limiting. The definitions have the effect of expanding the applicability of the protections under both titles by further delimiting their exception through the exclusion of individuals with a manifested disease diagnosed principally on genetic information. This implies that the diagnosis was not carried out in the context of, or made based on, the existence of signs or symptoms of the disease or disorder, and appears likely to

[97] 29 C.F.R. §1635.12, 75 *Federal Register* 68939 (November 9, 2010).

[98] P.L. 110-325. For a discussion of the ADAAA see CRS Report RL34691, *The ADA Amendments Act: P.L. 110-325*.

[99] 75 *Federal Register* 68931 (November 9, 2010).

[100] 74 *Federal Register* 51666 (October 7, 2009) and 75 *Federal Register* 68917 (November 9, 2010).

include those individuals with a manifested (i.e., diagnosed) genetic disease that is not yet substantially limiting (i.e., no substantial signs or symptoms).

Authorization of Appropriations and Effective Date

Such sums as may be necessary are authorized to be appropriated. The effective date of GINA was eighteen months after the date of enactment.

Title III—Miscellaneous Provisions

GINA includes a severability provision. If any provision of the act is declared unconstitutional, the remainder of the act is not to be affected. Title III also amended section 16(e) of the Fair Labor Standards Act[101] regarding child labor protections.

Issues for Consideration

The enactment of GINA continues to raise some issues for consideration. Educating the public and health care providers about the scope and application of GINA is important as implementation of the law continues. Recent data indicate that awareness of the law amongst the public is limited. A 2008 survey reported that, "only 16 percent of respondents to the survey knew that there were laws that protect the privacy of genetic information, and only one-quarter of those felt that protections were sufficient."[102] A similar survey conducted in 2010 found that awareness of laws protecting privacy held steady at 16%, with 77% of Americans unsure whether they are protected by law.[103] Educational efforts are particularly relevant because there are several limitations to the scope of the law of which the public and practitioners should be made aware in order to avoid confusion or misunderstanding.

Importantly, the scope of the law is limited to the settings of health insurance and employment. It does not cover the following: long term care insurance; life insurance; short-term disability insurance; or long-term disability insurance. Moving forward, this distinction may need to be presented clearly to the public, so there is not an expectation of blanket protection from genetic discrimination in all settings where genetic information may be disclosed, requested, required or used. The HHS final rule implementing Section 105 ("Privacy and confidentiality") of Title I extended certain of GINA's protections to additional types of health plans, as defined under the HIPAA Privacy Rule, to which GINA did not expressly apply. This expansion of GINA's applicability is limited to the prohibition on the use of health information, that is genetic information, for underwriting purposes, as required by Section105, and does not act to extend the protections established in Sections 101-104 of Title I to these additional health plan types. Additionally, the final rule does not apply this prohibition to issuers of long-term care insurance, although they are in the HIPAA Privacy Rule's definition of "health plan"; the final rule clarifies that this is due to a lack of evidence of the effect that prohibiting the use of genetic information in underwriting may have on long-term care insurance issuers.

[101] 29 U.S.C. §216(e).

[102] SACGHS, "Genetics Education and Training of Health Care Professionals, Public Health Providers, and Consumers," May 2010, http://oba.od.nih.gov/oba/SACGHS/SACGHS%20Draft%20Genetics%20Education%20and%20Training%20Report.pdf#page=56 on December 19, 2010.

[103] Council for Responsible Genetics, "Genetic Privacy Worries on the Rise," http://www.councilforresponsiblegenetics.org/genewatch/GeneWatchPage.aspx?pageId=324 on December 19, 2011.

In addition, GINA does not necessarily extend protections against discrimination in health insurance and employment to individuals with manifested diseases or disorders, genetic or otherwise. Specific provisions in Titles I and II clarify that health insurers and employers will not be in violation of GINA if they use specified information about, or knowledge of, a manifested disease or disorder to establish premiums, set enrollment eligibility or preexisting exclusion requirements, or make employment decisions (this is affected by passage of the ACA; see below). Again, educational efforts may be useful in ensuring that the public is aware of relevant limitations in the scope of the law.

Finally, the passage of the ACA appears to affect GINA, and Title I provisions in particular.[104] The ACA established a number of reforms to the private health insurance market, limiting insurers' ability in many cases to use health status or factors to discriminate in the issuance or renewal of policies. In addition, provisions in the ACA address employer wellness programs, and the information that such programs may collect from employees. This intersects with GINA in that family history or other genetic information may be requested by the employer in the context of such programs.

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[104] For more information about the potential interaction between GINA and the ACA in terms of both employment and health insurance, see CRS Report R41314, *The Genetic Information Nondiscrimination Act of 2008 and the Patient Protection and Affordable Care Act of 2010: Overview and Legal Analysis of Potential Interactions*, by Amanda K. Sarata and Jennifer A. Staman.